

EN

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Answer given by Ms Kyriakides  
on behalf of the European Commission  
(13.12.2021)

1. At present, there are no specific financial instruments attached to the portfolio<sup>1</sup>, however the relevant candidates will benefit from regulatory flexibility as set out in the Therapeutics Strategy, while making sure medicinal products are safe and effective.

2. In the context of the joint procurement agreement for medical countermeasures, the Commission concluded three framework contracts that facilitate access to promising therapeutics on monoclonal antibodies for the participating countries. The Commission continues discussions for other medicines. The portfolio of the promising therapeutics has been broadened to 10<sup>2</sup>. Two EU-wide marketing authorisations for COVID-19 therapeutics were granted in November 2021, two rolling reviews and four assessments of marketing authorisations are ongoing<sup>3</sup>.

3. The Commission already ensured access to the total quantity of therapeutics required by the countries, which participated in the joint procurements, as follows:

Company	Product (monoclonal antibodies)	Quantity
Hoffmann-La Roche	REGN-COV2 (combination of casirivimab and imdevimab)	55.000
GlaxoSmithKline (GSK)	VIR-7831 (sotrovimab)	220.000
Eli Lilly	Combination of bamlanivimab and etesevimab	220.000

The contracts foresee the possibility to purchase the products after they received an EU (conditional) marketing authorisation or a national emergency use authorisation. This ensures sufficient flexibility for rapid access to the therapeutics, while taking into account safety and efficacy.

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<sup>1</sup> [https://ec.europa.eu/commission/presscorner/detail/en/qanda\\_21\\_3301](https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_3301)

<sup>2</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_5366](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5366)

<sup>3</sup> <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-treatments>